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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,454	11/01/2001	Laura McCulloch	JBP-527	4007
27777	7590	03/10/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			JOYNES, ROBERT M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,454

Applicant(s)

MCCULLOCH ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-27, 29-38 and 42-51 is/are pending in the application.
- 4a) Of the above claim(s) 7, 28, 39-41 and 52-55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-27, 29-38 and 42-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on December 10, 2003.

Election/Restrictions

Newly submitted claims 53-55 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original methods claims are drawn to method of *treating* dermatitis whereas the new methods of Claims 53-55 are drawn to preventing. This is a new method and therefore a new invention. Prevention and treating are not one if the same. Reduction of dermatitis is interpreted as treatment, not prevention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 53-55 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-27, 29-38, 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minerath, III et al. (US 6551607 B1) in combination with Hartung et al. (US 5436007).

Minerath teaches methods and compositions for sequestering skin irritants comprising a substrate containing a sequestering agent with an affinity for skin irritants (Col. 3, lines 55-66). The skin irritants are present in nasal secretion, bodily waste or the external environment (Col. 6, lines 45-47). The material suitable for the substrate for the composition includes woven and non-woven webs, fabric, scrims, synthetic fibers and natural fibers (Col. 9, line 14 – Col. 10, line 44). The substrate can contain both hydrophobic and hydrophilic sequestering agents (Col. 6, lines 47- 54). The hydrophilic sequestering agents are chosen from clays, talc, diatomaceous earth, silica, calcium sulfate and the like (Col. 7, lines 24-58; Col. 16, lines 9-40). The hydrophobic sequestering agents are chosen from modifications of the native sequestrants (Col. 7, line 59 – Col. 8, line 14; Col. 16, lines 9-40). The compositions taught can also include lipophilic sequestering agents, humectants, emulsifying surfactants and viscosity

enhancers as well as buffering agents, additional active agents, fragrances, dyes, sunscreens, deodorants and combinations thereof (Col. 10, line 54 – Col. 13, line 44).

Minerath does not expressly teach what the exact additional components, such as buffering agents or fragrances, can be in the composition.


Hartung teaches a skin composition that can be delivered to the skin via a wipe or diaper that comprises sodium citrate as a buffering agent (Col. 3, lines 45-59). Hartung also teaches that EDTA can be present in the compositions as a viscosity enhancer (Col. 5, lines 29-62). The wipes or diapers of the reference are used to treat diaper rash, which is caused by bodily waste (Col. 6, lines 28-34). EDTA is one member of the Markush group that defines the peptizing agent.

Neither reference teaches the exact concentration ranges or ratios for components of the composition.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate EDTA into a skin care composition as a viscosity enhancer.

With respect to the claimed concentration ranges, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

One of ordinary skill in the art would have been motivated to do this to prepare a topical composition wherein the viscosity of the composition is suitable for topical composition to provide the most suitable delivery of the composition to the skin.



Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed December 10, 2003 have been fully considered but they are not persuasive. Applicants argue that the prior art does not teach the inclusion of what applicants call peptizing agents. While the Examiner pointed out one such peptizing agent in the instant Markush group, applicants have amended their claims to now exclude that single member of the group. The prior art also teaches that the compositions can include EDTA, which is also a member of the instant Markush group. Therefore, the prior art still renders obvious the instant claims. Applicants arguments to the contrary are unpersuasive.

Allowable Subject Matter

Claim 51 is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes


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